Drug and Therapeutics Committee
Training Course

Session 11.
Drug Use Evaluation

Participants’ Guide
This document was made possible through support provided by the U.S. Agency for International Development, under the terms of cooperative agreement number HRN-A-00-00-00016-00. The opinions expressed herein are those of the author(s) and do not necessarily reflect the views of the U.S. Agency for International Development.

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Developed in Collaboration with the
World Health Organization
Geneva, Switzerland
### ABBREVIATIONS AND ACRONYMS

<table>
<thead>
<tr>
<th>Abbreviation</th>
<th>Definition</th>
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</thead>
<tbody>
<tr>
<td>ADR</td>
<td>adverse drug reaction</td>
</tr>
<tr>
<td>AMR</td>
<td>antimicrobial resistance</td>
</tr>
<tr>
<td>bid</td>
<td>bis in die (twice a day)</td>
</tr>
<tr>
<td>CrCl</td>
<td>creatinine clearance</td>
</tr>
<tr>
<td>DTC</td>
<td>Drug and Therapeutics Committee</td>
</tr>
<tr>
<td>DUE</td>
<td>drug use evaluation</td>
</tr>
<tr>
<td>DUR</td>
<td>drug use review (per CPM word list)</td>
</tr>
<tr>
<td>GI</td>
<td>gastrointestinal</td>
</tr>
<tr>
<td>h</td>
<td>hour</td>
</tr>
<tr>
<td>IM</td>
<td>intramuscular</td>
</tr>
<tr>
<td>iv or IV</td>
<td>intravenous</td>
</tr>
<tr>
<td>kg</td>
<td>kilogram</td>
</tr>
<tr>
<td>mg</td>
<td>milligram</td>
</tr>
<tr>
<td>ml</td>
<td>milliliter</td>
</tr>
<tr>
<td>MSH</td>
<td>Management Sciences for Health</td>
</tr>
<tr>
<td>MUR</td>
<td>medicine use review</td>
</tr>
<tr>
<td>NSAID</td>
<td>non-steroidal anti-inflammatory drug</td>
</tr>
<tr>
<td>po</td>
<td>per os (by mouth)</td>
</tr>
<tr>
<td>q</td>
<td>quart</td>
</tr>
<tr>
<td>STG</td>
<td>standard treatment guideline</td>
</tr>
<tr>
<td>UTI</td>
<td>urinary tract infection</td>
</tr>
<tr>
<td>VA</td>
<td>visual aid</td>
</tr>
<tr>
<td>VEN</td>
<td>vital, essential, nonessential</td>
</tr>
<tr>
<td>WHO</td>
<td>World Health Organization</td>
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SESSION 11. DRUG USE EVALUATION

Purpose and Content

Session 11 provides information on the concept of drug use evaluation (DUE), a quality assurance method that is used worldwide, especially in North America and Europe, and that has been shown to be effective in identifying medicine use problems and as a method to improve medicine use. A broad-based, ongoing, systematic DUE program is valuable in promoting and improving rational use of medicines in hospitals and clinics.

Objectives

After attending this session, participants will be able to—

- Understand the concept of DUE
- Understand the process for implementing and performing a DUE
- Discuss the use of a DUE for improving pharmaceutical therapy
- Prepare criteria and thresholds for a DUE

Preparation and Materials

Read the following—

- Participants’ Guide

Key Definition

**Drug use evaluation (DUE)**—An ongoing, systematic, criteria-based program of medicine evaluations that will help ensure appropriate medicine use. If therapy is determined to be inappropriate, interventions with providers or patients will be necessary to optimize pharmaceutical therapy. This terminology is similar to that drug use review (DUR) and medication use review (MUR).

Introduction

The Drug and Therapeutics Committee (DTC) is responsible for many important pharmaceutical management activities; two of the most important ones are identifying medicine use problems
and implementing strategies to alleviate these problems. All DTCs should be actively involved in the evaluation and selection of new medicines for the formulary and the provision of these medicines to practitioners. It must also ensure that these medicines are being used correctly so that patients receive the maximum benefit from their pharmaceutical therapy.

Many strategies can be implemented to improve medicine use including educational programs, standard treatment guidelines (STGs) and other managerial activities, and regulatory programs. Session 11 provides participants with more in-depth information concerning the important managerial strategy of DUE. A DUE will—

- Define appropriate medicine use (by establishing approved criteria)
- Audit criteria against what is being prescribed
- Provide feedback to prescribers on all identified problems
- Monitor to see if criteria are followed and prescribing is improved

**The Need for DUE**

Irrational medicine use has occurred for as long as medicines have been available. In treating patients with modern medicines, several choices of therapy are available—rather than just one that all providers must follow. This increased number of medicines and treatment options serves to increase the number of irrational medicine treatment encounters and, ultimately, poor patient outcomes. Casual observation, as well as more systematic study of prescribing practices, frequently reveals a pattern of diversity among prescribers in the treatment of even the most common conditions.

Polypharmacy is one problem; providers may use three, four, five, and sometimes more medicines to treat the most trivial conditions for the sake of satisfying a patient’s need to receive medicines (or the pharmaceutical seller’s need for profit). Other reasons for polypharmacy include lack of diagnostic competence or confidence and an inadequate knowledge of treatment regimens. Other common medicine use problems are choosing incorrect medicines, prescribing the incorrect dose, prescribing medicines that cause adverse drug reactions (ADRs) or medicine interactions, and using more expensive medicines when less expensive medicines would be equally or more effective. Other medicine use problems that suggest a need for DUE include the following—

- Problems indicated from World Health Organization (WHO)/Management Sciences for Health (MSH) indicator studies
- High number of ADRs
- Signs of treatment failures
- Excessive number of nonformulary medications used
• Use of high-cost medicines where less expensive alternatives exist

• Excessive number of medicines within a therapeutic category

DUE, a system of improving the quality of medicine use in hospitals and clinics, is an ongoing, systematic, criteria-based program of medicine evaluations that will help ensure that appropriate medicine use is provided. A DUE can be structured so that it will assess the actual process of administering or dispensing a medicine (i.e., appropriate indications, dose, medicine interactions) or assess the outcomes (i.e., cured infections, decreased lipid levels.) Objectives of a DUE are as follows—

• Ensuring that the pharmaceutical therapy meets current standards of care
• Promoting optimal medication therapy
• Preventing medication-related problems
• Identifying specific medicine use problems that require further evaluation
• Creating guidelines (criteria) for appropriate medicine use
• Defining thresholds for quality of medicine use
• Enhancing accountability in the medicine use process
• Controlling pharmaceutical cost

A DUE system can be established in a short period once it has become clear what medicine use problems exist. Many of these problems can be identified from other DUE studies, a review of aggregate data in the hospital (e.g., most costly medicines, most prescribed medicines, ADR records), medical chart reviews, hospital and clinic medicine use indicators, or recommendations of DTC members. Regular meetings of the DTC and assessments of quality measurements in the health care system should be able to identify problems that can be addressed in a DUE for resolution.

A Stepwise Approach to DUEs

The following eight steps outline the basic information necessary to start and maintain a DUE program.

**Step 1. Establish Responsibility**

Responsibility falls to the DTC or a subcommittee of the DTC that functions only to monitor DUEs in the hospital or clinic. The DTC should undertake this responsibility with considerable interest, because this process can solve many medicine use problems, as has proven to be the case in many countries where this quality assurance function has been fully utilized.

The DTC or a subcommittee must establish procedures that will govern the committee in its activities concerning medicine use review and evaluation. As part of the responsibility of the DUE function, the DTC must establish a plan, outlining which medicines will be a part of the DUE process. This plan needs to be updated and evaluated each year.
Step 2. Develop Scope of Activities

The DTC should assess and identify medicine use problems and using this information to develop a scope of activity for the DUE program. The scope can be extensive or it can focus on a single aspect of pharmaceutical therapy. Methods to identify medicine use problems include and ABC or vital, essential, nonessential (VEN) analysis, defined daily dose analysis, ADR reports, medication error reports, antibiotic sensitivity results, procurement studies, hospital and primary care clinic indicator studies, patient complaints or feedback, and staff feedback. These screening mechanisms serve to provide the DTC with information concerning medicine use that would need further evaluation in a DUE.

Because of the large number of medicines available at a hospital or clinic, the DTC must concentrate on the most important medicines, those with the highest potential for problems, to get the most return on the work involved. These high priority areas would include—

- High-volume medicine use
- Medicines with a low therapeutic index
- Medicines with a high incidence of ADRs
- Expensive medicines
- Medicines that are critically important, including those in the following categories: cardiovascular, emergency, toxicology, oncology, intravenous medicines, and narcotic analgesics
- Antimicrobial medicines, both prophylactic and therapeutic
- Injections
- Medicines undergoing evaluation for addition to the formulary
- Medicines used for off-label indications
- Medicines used for high-risk patients

Steps 3 and 4. Establish Criteria, Define and Establish Thresholds

Criteria are statements that define correct medicine use. Establishing criteria is the single most important procedure in a DUE. Criteria for the use of any medicine should be established by the DTC using relevant evidence-based literature sources and recognized international and local experts. The criteria for any DUE should reflect what is in the country’s STGs (assuming that they have been developed correctly) and any medicine-use protocols that exist. Credibility of the DUE relies on criteria that are based on evidence-based medicine. Criteria must be developed with and accepted by the medical staff for the process to be credible.
Criteria should be developed for three to five of the most important indicators for each aspect of medicine use. Reviewing larger numbers of indicators will make for a more difficult DUE process and may significantly impair the outcomes of the review. This is not to say that more extensive use of indicators should not be reviewed, only that results are more easily obtained and possibly more meaningful when the scope is narrowed to include only the most important aspects of care.

After developing criteria, the DTC must establish a threshold or standard (benchmark) against which the criteria will be judged. A threshold refers to the percentage of charts or records that will meet or exceed the established criteria for the medicine. Ideally, this threshold will be 100 percent, but realistically, a smaller percentage will be more appropriate to account for exceptions to routine medicine prescribing. Therefore, a threshold of 90 to 95 percent is typically used for many criteria, but each instance must be carefully analyzed before reaching a conclusion.

A comprehensive list of indicators for appropriate medicine use includes the following components (see table 1 for an example of application)—

- **Process indicators**
  - Indications—specific uses for the medicine in question
  - Dose—specific doses for any approved indication for appropriate duration
  - Quantity dispensed—correct number of doses administered
  - Preparation—steps involved with preparing a medication for administration
  - Monitoring—laboratory test necessary and intervals of testing during the use of the medicine
  - Contraindications—known contraindications
  - Drug interactions—significant medicine interactions, including medicine-medicine, medicine-food, and medicine-laboratory
  - Administration—specific steps necessary to administer a medicine, especially for injectables
  - Patient education—instructions and education that a patient should receive with the medicine

- **Outcome indicators**—specific outcomes to be realized from medicine use
  - Lowered blood pressure, stabilized blood glucose, and fewer migraine and asthma attacks
  - Decreased visits to the emergency room, decreased hospitalizations
- Improved patient quality of life (obtained from questionnaires)

- Pharmacy administration indicators
  - Correct cost to patient
  - Accurate billing records
  - Accurate dispensing records
  - Appropriate use of generic medicines or therapeutic equivalents
  - Appropriate use of formulary medicines
  - Appropriate quantity dispensed

### Table 1. Sample DUE Criteria for Ciprofloxacin

<table>
<thead>
<tr>
<th>Indicator</th>
<th>Criteria</th>
<th>Threshold, %</th>
</tr>
</thead>
<tbody>
<tr>
<td>Indication</td>
<td>Complicated, chronic, or relapsing urinary tract infection (UTI)</td>
<td>90</td>
</tr>
<tr>
<td></td>
<td>Gonorrhea</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Resistant respiratory tract infections</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Bone and joint infections</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Prostatitis</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Gastrointestinal (GI) infections</td>
<td></td>
</tr>
<tr>
<td>Dose</td>
<td>Complicated or recurrent infections: 500–750 mg bid</td>
<td>95</td>
</tr>
<tr>
<td></td>
<td>GI infections: 500 mg bid</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Gonorrhea: 250 mg in 1 dose</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Dose in renal disease decrease as follows:</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Creatinine clearance (CrCl) 30–50 ml/min</td>
<td></td>
</tr>
<tr>
<td></td>
<td>– 250–500 q 12 h 5–29 ml/min</td>
<td></td>
</tr>
<tr>
<td></td>
<td>– 250–500 q 18 h</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Hemodialysis—500 mg q 24 h</td>
<td></td>
</tr>
<tr>
<td>Duration</td>
<td>Complicated UTI: 10–21 days</td>
<td>95</td>
</tr>
<tr>
<td></td>
<td>Respiratory: 7–14 days</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Osteomyelitis: 4–6 weeks</td>
<td></td>
</tr>
<tr>
<td></td>
<td>GI infection: 5 days</td>
<td></td>
</tr>
<tr>
<td>Contraindications</td>
<td>Pregnancy</td>
<td>100</td>
</tr>
<tr>
<td></td>
<td>Children younger than 18</td>
<td></td>
</tr>
<tr>
<td>Medicine interactions</td>
<td>Medicines—theophylline, antacids, iron, sucralfate, probenecid</td>
<td>90</td>
</tr>
<tr>
<td></td>
<td>Food: decreased absorption with milk</td>
<td></td>
</tr>
<tr>
<td>Outcome</td>
<td>Negative cultures</td>
<td>90</td>
</tr>
<tr>
<td></td>
<td>Improved symptomatology</td>
<td></td>
</tr>
<tr>
<td></td>
<td>No treatment failures</td>
<td></td>
</tr>
</tbody>
</table>
Step 5. Collect Data and Organize Results.

DUEs can be accomplished as prospective evaluations, or they can be performed retrospectively. A prospective analysis involves the collection of data as the medicine is being prepared or dispensed to the patient. Retrospective analysis is done using chart reviews or other data sources to review medicine use according to indicators and criteria prepared in advance. The advantage of a prospective review is that the pharmacist (or other reviewer) can intervene at the time the medicine is dispensed to prevent errors, for example, dosage, indications, or interactions. Retrospective evaluation, which may involve more of the reviewer’s time or require access to medical records, is best accomplished when the reviewer has time away from the patient care areas and distractions. Typically, medicine-related criteria that are reviewed in these types of evaluations are as follows—

- Prospective studies (obtained from prescription records)
  - Indication
  - Dose
  - Duration of therapy
  - Dosage form and route of administration
  - Potential medicine interactions
  - Appropriate therapy and medicine selection (corresponds to STGs)
  - Therapeutic duplication
  - Contraindications
  - Quantity dispensed

- Retrospective studies (obtained from prescription, medical records, laboratory records)
  - Laboratory monitoring
  - Monitoring therapeutic use of high-cost medicines
  - ADRs to medications
  - Correct use of generic or therapeutic equivalents
  - Patient outcomes from pharmaceutical therapy

Collection of the data is performed by reviewing a suitable sample of charts or prescription records from the health care facility, usually by selected pharmacy personnel. At a minimum, 50 to 75 records should be reviewed at each health care facility. The larger the facility and the more practitioners who are available, the larger the percentage of records that would need to be reviewed and analyzed.

An illustrative sample of a collection form, indicators, criteria, and thresholds can be found in annex 1.

In some countries, computerized systems automatically address the criteria in the process of entering patient information into the computer. Pharmacists then must evaluate any indicators that do not meet established criteria (i.e., dose, medicine interactions, duplicate medicines in the same therapeutic class, and others that may appear in the patient records in the computer program). These problems then must be corrected before the medicine is dispensed. This system
is also useful because of the large number of patients that can actually be evaluated and the subsequent database that would be produced.

**Step 6. Analyze Data**

Data are collected, tabulated, and analyzed to see if criteria and thresholds are met. The following important steps should be completed when analyzing data—

- Tabulate results for each indicator
- Analyze results to see if the criteria are met and the thresholds are not exceeded
- Determine why thresholds are not met
- Analyze data quarterly or more frequently

If a threshold is not met, it may indicate a medicine use problem that requires the attention of the DTC.

**Step 7. Develop Recommendations and Action Plan**

After completing the data analysis, information is presented to the DTC and a decision is made as to the appropriateness of the information in the DUE. The DTC also must decide on whether to continue, discontinue, or expand the functions of the DUE in question. All medicines that do not meet the thresholds must be evaluated carefully and plans must be made to improve the use of the medicine relative to the criteria.

Recommendations should be prepared for the DTC to address the following—

- Inappropriate medicine use
- Unacceptable patient outcomes
- Methods to resolve any medicine use problem

Recommendations should include specific steps to correct any medicine use problem that is evident from performing the DUE. For example, if a specific medicine is being prescribed at a high dose, then the recommendations need to reflect this and how the DTC might improve the dosing of this medicine. Interventions to improve medicine use might include—

- Education, including letters to practitioners, in-service education, workshops, newsletters, and face-to-face discussions
- Implementation of medicine order forms
- Prescribing restrictions
- Formulary manual changes
- Change (or better enforcement) of the STGs
Step 8. Conduct DUE Follow-up

Follow-up in every DUE is critical to ensure resolution of any unresolved medicine use problems. The DUE may have identified new problems that need to be resolved within the health care system. If the problems are not resolved, then the DUE will have little usefulness to the health care system. As a part of a follow-up plan, the DTC must assess the need to continue, modify, or stop the DUE activity depending on the results of each specific medicine review.

A DUE should be an ongoing process in which medicine-related problems are regularly addressed. Medicine review should be considered a long-term program, one that is continuously updated and revised to reflect current situations and needs within the health care institution.

All programs within the DTC should be evaluated yearly. This complete evaluation is necessary to look comprehensively at the entire program and analyze its merits and its utility in improving medicine use. Programs that do not have a significant impact on medicine use should be redesigned so that they can provide measurable improvements. Without improvements in medicine use and patient outcomes, the time spent on DUE will be of no value.

It must be stressed that indicators and criteria for a DUE can be highly individualized depending on the specific needs of the health care facility.

When DUEs Go Wrong

Some problems in the DUE procedure will serve to make this process ineffective. Because it is a complicated, multifactorial process, it may easily get bogged down and become an ineffective evaluation. Some of the difficulties and their solutions are—

- Lack of authority and organization—The DUE must have a clear organizational structure defined including, for example, what person develops criteria, collects data, and reports results. Clinicians must be involved in the development.

- Poor problem prioritization—Poor prioritization may lead to work on medicine use problems that may be insignificant and make meaningful results difficult to obtain.

- Poor documentation—All activities should be documented with a report in the DTC minutes, and this report should be distributed to the medical staff as necessary; documentation should clearly discuss results and recommendations of each DUE.

- Inadequate follow-up—This problem is one of the most frequent to occur with DUE; follow-up and resolution of every problem must be accomplished with every DUE.
- Overly intrusive data collection and evaluation—This process can consume many individuals’ time and must be kept to a minimum to accomplish the task of the DUE; DUEs in general must not take a significant amount of time away from patient care.

- Failure to obtain “buy in” from medical staff

The performance of a DUE must be kept in perspective at all times. If a DUE becomes very time-consuming with only minimal results, then the methodology must be changed and the DUE restructured (in terms of criteria, data collection, and interventions) to provide meaningful results. The objectives of all DUEs are to identify and correct medicine use problems and consequently improve patient outcomes. A DUE should never become just an exercise in collecting and disseminating information.
Activity 1. Developing a DUE

For activity 1, assume that your DTC has information derived from indicator studies, chart reviews, and ABC analysis that shows that many antimicrobial medicines are being used inappropriately (see Activity 1. Developing a Guideline for Use during the Field Trip in session 10, “Standard Treatment Guidelines”). There are anecdotal reports of inappropriate use (e.g., wrong dose, wrong combination of medicines, lack of baseline laboratory studies) for several antimicrobial medicines.

The DTC has revised the STGs for treating pneumonia and for surgical prophylaxis. The DTC has also provided extensive education to physicians and nurses concerning appropriate treatment including face-to-face education and in-service education programs. Because this problem is significant, the DTC recommends that a DUE be implemented to assess and confirm that the educational activities and revised STGs have effectively changed prescribing habits.

Each group should develop DUE criteria and thresholds for the antimicrobials that are a part of the STG for pneumonia or caesarian section prophylaxis.

Summary

DUE is an audit and feedback intervention in which medicine use can be reviewed against approved criteria. A DUE requires the establishment of criteria and thresholds and the review of medicine use to determine if therapy is appropriate. Feedback to prescribers is necessary to improve prescribing and educational, managerial, and regulatory interventions may be required to improve the use of medicines.

A DUE will help improve medicine use by—

- Ensuring that the pharmaceutical therapy meets current standards of care
- Promoting optimal medication therapy
- Preventing medication-related problems
- Identifying specific medicine use problems that require further evaluation
- Creating guidelines (criteria) for appropriate medicine use
- Define thresholds for quality of medicine use
- Enhancing accountability in the medicine use process
- Controlling medicine cost

DUE methodology has been successful in many parts of the world. By using appropriate planning, development, and follow-up and by implementing appropriate interventions when problems are discovered, improved patient outcomes will be the result.
Annex 1. Example of Established DUE Criteria on Data Collection Form for Amikacin

<table>
<thead>
<tr>
<th>Date:</th>
<th>Medicine: AMIKACIN</th>
<th>Data collector’s initials: ________________</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Patient Chart No.</td>
<td>Diagnosis</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Criteria and Indicators</th>
<th>Threshold</th>
<th>Observed</th>
</tr>
</thead>
<tbody>
<tr>
<td>Justification for medicine being prescribed</td>
<td>95%</td>
<td>Yes No</td>
</tr>
<tr>
<td>1. Serious infections caused by susceptible strains of aerobic gram-negative bacteria resistant to gentamicin and tobramycin</td>
<td></td>
<td>Yes No</td>
</tr>
<tr>
<td>2. Suspected serious gram-negative infections acquired in the hospital with high resistance rates to gentamicin and tobramycin</td>
<td></td>
<td>Yes No</td>
</tr>
<tr>
<td>3. In combination with an antipseudomonal penicillin when treating serious pseudomonas infections</td>
<td></td>
<td>Yes No</td>
</tr>
<tr>
<td>Process criteria</td>
<td>100%</td>
<td>Yes No</td>
</tr>
<tr>
<td>4. Obtain serum creatinine before therapy or within 24 hours of initiation of therapy</td>
<td></td>
<td>Yes No</td>
</tr>
<tr>
<td>5. Loading dose of 7.5 mg/kg (IV or IM) based on ideal body weight</td>
<td>100%</td>
<td>Yes No</td>
</tr>
<tr>
<td>6. Maintenance dosage range of 15 mg/kg/day ideal weight (exception: renal compromise)</td>
<td>100%</td>
<td>Yes No</td>
</tr>
<tr>
<td>7. Therapy changed to tobramycin, gentamicin, or other medicine if culture and sensitivity indicate less expensive or more appropriate medicine</td>
<td>100%</td>
<td>Yes No</td>
</tr>
<tr>
<td>Outcome criteria</td>
<td>90%</td>
<td>Yes No</td>
</tr>
<tr>
<td>8. Clinical improvement noted in patient medical records</td>
<td></td>
<td>Yes No</td>
</tr>
<tr>
<td>9. Fever reduction to normal within 72 hours</td>
<td></td>
<td>Yes No</td>
</tr>
</tbody>
</table>
